REMARKS

By the above actions, claim 1 has been amended to incorporate the subject matter of claim 7 so as to now constitute original claim 7 in independent form. Accordingly, claim 7 has been canceled. Furthermore, the specification has been amended to reflect the patent numbers of the applications referenced on pages 4-8 of the specification. In view of these actions and the following remarks, reconsideration of this application is now requested.

Claims 1 & 2 were rejected under 35 U.S.C. § 102 as being anticipated by the disclosure of the Langer patent. However, this rejection has been rendered moot by the amendment of claim 1 to now constitute claim 7 in independent form. Thus, this rejection should be withdrawn.

Claims 1-17, 20 & 22 were rejected under 35 U.S.C. § 103 as being unpatentable over the Baumann et al. patent when viewed in combination with the Langer and Engebretson et al. patents, while claims 18, 19, & 21 were rejected on this basis in view of these references when considered further in light of the Berran et al. patent. Reconsideration of these rejections are in order for the following reasons.

Firstly, in making these rejections, the Examiner has failed to specifically address the language of original claim 7 that "the energy storage is disposed directly within the first chamber without the provision of a separate energy storage housing." Furthermore, the Examiner's comments fail to indicate any reason why such a feature might be obvious in view of the teachings any of the applied patents, either singly or in combination. In fact, not only is there no express teaching of this feature in any of the applied patents, but instead there is a basis for concluding that such a construction as disclosed and claimed by the present applicant would not be adopted.

In particular, as is clearly shown in Figs. 2 & 4 of the Baumann et al. patent, the battery (direct voltage source 25) is hermetically sealed within the same compartment as the charging electronic device 30 and the telemetry circuit 38. Those of ordinary skill in the art would recognize that the battery 25 could not be disposed directly within the same chamber as the charging electronic device 30 and the telemetry circuit 38 without the battery being provided with a separate energy storage housing since to do so would result in the charging electronic device and the telemetry circuit being damaged by the battery. Furthermore, while the present applicant discloses that dispensing of the separate housing for the battery is

advantageous in the context of applicant's process and device because it "facilitates production of the system" (page 16, paragraph [0047], first sentence), there is nothing to indicate that such a result would be obtained from direct placement of their battery in its compartment without of separate housing of its own given that the battery shares a compartment with the charging electronic device 30 and the telemetry circuit 38 as contrasted with the arrangement of the present invention where such components are in a different compartment from the battery.

Similarly, the Langer patent shows in Fig. 3 that a pair of batteries 26 share the same compartment with capacitors 24 and the hermetic sealing disclosed in this patent is of the overall housing itself and of the individual batteries 26. In this regard, the Examiner may have been mislead by the statement cited in column 2 due to the absence of the page containing columns 3 and 4 of the Langer patent (both the copy furnished by the Examiner with his Office Action and that in the USPTO electronic database images lack that page, so that a copy of the missing page has been acquired from the EPO's full text database). As the Examiner will note, lines 1 and 2 of column 3 and third paragraph of column 4 indicate that each of the batteries 26 are hermetically sealed and thus must each have its own housing as opposed to being disposed directly in the compartment without their own housings. Furthermore, the hermetically sealed batteries are described as being wrapped together with the capacitors and it is the housing 12 which is hermetically sealed and coated with a hydrogen getter to prevent the escape of gases produced by the capacitors which are not themselves hermetically sealed (see, column 2, lines 35-43). Thus, Langer cannot suggest modifications to Baumann et al. that would lead to the present invention and only serves to reinforce the nonobviousness of the subject matter of original claim 7 and amended claim 1.

As for the Engebretson, as is clear from Fig. 3 and the description thereof in the first full paragraph of column 5, the battery 34 is mounted to the circuit board 34 to which the microphone 36, receiver 38, electronic circuitry 40 and recharging circuit 41 are also mounted. Furthermore, the battery 34 appears to be at least partially external of the package 28. As a result, nothing can be derived from Engebretson which would overcome the above mentioned deficiencies of the Baumann et al. and Langer disclosures relative to the claimed invention of the present applicant, and only can be said to lead further away from it since a battery positioned as shown and mounted to the circuit board for the electronics would have

to have be enclosed within its own casing.

With regard to the Berrang et al. reference, which the Examiner relies upon solely for a showing of an external coil, feed-through contacts and the use of biocompatible polymers also is unable to make up for the shortcomings of the Baumann et al. Langer and Engebretson et al. references. Fig. 2 clearly shows that the battery is not housed by itself and the reference to the use of commercially available batteries makes it clear that the use of conventional batteries having their own sealed casing is contemplated.

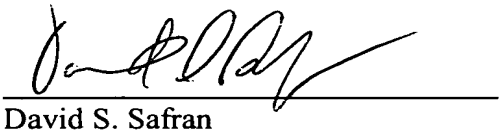
Accordingly, since none of the references, viewed singly or in combination can suggest an implantable hermetically sealed housing a hermetically tight separation wall which divides the housing into a first chamber for housing a storage for electrical energy for supplying electric current to the medical device and a second chamber for housing the electronics and in which the energy storage is disposed directly within the first chamber without the provision of a separate energy storage housing, the outstanding rejections under § 103 should be withdrawn and such action is now requested.

The prior art that has been cited, but not applied by the Examiner has been taken into consideration during formulation of this response. However, since this art was not considered by the Examiner to be of sufficient relevance to apply against any of the claims, no detailed comments thereon are believed to be warranted at this time.

While the present application is now believed to be in condition for allowance, should the Examiner find some issue to remain unresolved, or should any new issues arise, which could be eliminated through discussions with applicant's representative, then the Examiner is invited to contact the undersigned by telephone in order that the further prosecution of this application can thereby be expedited.

Lastly, it is noted that a separate Extension of Time Petition accompanies this response along with payment of the requisite extension of time fee. However, should that petition become separated from this Amendment, then this Amendment should be construed as containing such a petition and the required payment applied to Deposit Account No. 192380 (740105-75)

Respectfully submitted,



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cylindrical capacitors 24 and a pair of hermetically sealed batteries 26 arranged one next to the other in a straight line.

Within the case 12, and above the battery-capacitor arrangement, is positioned an inner case 28, which comprises a lid 30 and body portion 32. When the lid 30 and the body portion 32 of the inner case 28 are joined together in a manner described hereinafter, they form a second hermetically sealed chamber 34. Housed within the chamber 34 is a pair of printed circuit boards 36 and 37, which contain the implantable defibrillator's logic circuitry, generally designated as 38. For purposes of the preferred embodiment, logic circuitry 38 takes the form of the defibrillator circuitry disclosed in the aforementioned patents. A conformal coating 31, such as molded silastic preform, acts to bind the printed circuit boards 36 and 37 against the inner case 28 to prevent any unwanted motion of the boards within the inner case.

For purposes of this discussion, the logic circuitry 38 comprises a fibrillation detector circuit, a charging circuit for charging the capacitors 24 to a level capable of defibrillating a malfunctioning heart, and discharging circuitry, responsive to the detection of fibrillation, for initiating the discharge of the charged capacitors 24 into the heart of a wearer.

On the top of lid 16 there are a pair of electrode terminals 40, which are contained within a epoxy-molded portion 42. The electrode terminals provide a means to which are connected the free ends of a pair of implanted leads (not shown), which have been inserted into a heart. These leads perform two functions: the transmission of ECG signals from the heart to the defibrillator, and the transmission of a defibrillating shock from the defibrillator to the heart. As will be described in greater detail hereinafter, the defibrillator contains additional structure for operatively associating the defibrillator logic circuits 38 with the capacitors 24, batteries 26, and electrode terminals 40.

When assembled, the hermetically sealed outer case 12 of the implantable defibrillator 10 ensures that none of the biological fluids and gases present at the implant site are permitted to enter the chamber 18. In like manner, hermetically sealed case 12 prevents any fluids or gases which could be released by the capacitors 24 from entering the human body. Specifically, the hermetically sealed inner case 28 isolates the logic circuits 38 from the capacitors 24, which are not, themselves, hermetically sealed.

A detailed description of a preferred embodiment will now be provided with reference to FIGS. 1, 3 and 4. The outer case 12 is typically made from titanium to assure adequate inertness to biological fluids and gases at the implant site. The case 12 comprises a body 14 which is preferably seamless in nature, and is produced by any of the well-known extrusion processes. Body 14 is defined by a pair of substantially parallel planar wall portions 44 and 46, which merge at their sides in cylindrically curved portions 48 and 50. The walls 44 and 46 and the curved portions 48 and 50 define a peripheral ledge 52. The other end of walls 44 and 46 are joined by a curved portion 54. The curved portion 54 merges in a smooth and continuous fashion with the curved sides 48 and 50 at corner portions 56 and 58.

The overall shape of the outer case 12 is designed to accomplish two purposes. The first is to provide a compact case of minimal size for housing the components and assemblies therein; the second is to provide an exterior configuration relatively devoid of sharp edges to prevent internal bruising of the wearer at the implant site.

Typically, the first component placed within the chamber 18 of the housing 12 is a test load resistor 20, which, as viewed in FIGS. 1, 3 and 4, is received in the case in cradling relationship with the interior wall of curved portion 54. A filling material (not shown) is then introduced into the chamber 18 to a height sufficient to just cover the test load resistor 20. The filling material is typically epoxy filled with glass microspheres, although silicon rubber and foam elastomer can also be used.

On top of the resistor 20 within the casing 12, there is placed an insulator 22. The insulator 22, which is a vacuum-formed component made of a suitable plastic, contains two well regions 60 and 62 defined by walls 64 and 66, respectively, for receiving the cylindrical capacitors 24 which are typically of the aluminum hydrolyte type. The walls 64 and 66 define a region which provides a snug fit for the bottoms of the capacitors 24 within the insulator 22. When in place, the capacitors 24 provide a space between themselves for containing the batteries 26. The batteries 26 are of the lithium anode type, are hermetically sealed, and are individually insulated by being wrapped in a high dielectric tape 68. The insulator 22 contains a pair of recesses 70, and a generally planar top surface 72 for receiving and supporting the batteries 26.

When assembled, the capacitors 24, batteries 26, and insulator 22 are wrapped in a plastic tape 74. The tape 74, which typically has a high dielectic, performs an insulating function between the interior wall of the body 14 and the capacitors 24 and batteries 26. The placement of the batteries 26 and the capacitors 24, as well as the configuration of the body 12, have been carefully chosen to provide a compact housing structure for these components in which the body 12 surrounds and supportively contacts the cell-capacitor arrangement. No space is lost since the rounded edges 48 and 50 conform to and mate with the cylindrical surfaces of the capacitors 24. Any dangers of battery leaking, venting or releasing of gases is minimized through the use of hermetically sealed batteries, which, as stated before, are wrapped in insulating tape 68. Further, the inner surface of the chamber 18 is covered with a suitable film or coating 33 that acts as a hydrogen getter to absorb any of the hydrogen which could be released from the capacitors 24.

The specific structure and contents of the inner case 28 will now be described. As viewed in FIGS. 1, and 3 through 5, the inner case 28 contains a lower lid 30 having a peripheral contour similar to that of the interior wall of the outer case 12. Contained within the peripheral boundary of the lid is a relatively planar portion 84. A wall portion 85 extends upwardly from the base portion 84 about the periphery of the lid. Disposed on the base portion 84 are four solid feed-throughs 86-89 and four tubular feed-throughs 91-94. All of the feed-throughs include an insulator member 150 to provide a hermetic sealing between the chamber 34 inside the inner case 28 and the chamber 18 within the outer case 12. Each of feed-throughs 86-89 contains a wire, or pin, 152 passing therethrough and extending a predefined distance within the chamber 34 of the inner case 28, and into the outer chamber 18 of the outer case 12. The positive lead of batteries 26 is connected to the wire of feed-through 87, while the negative lead of